

REMARKS

This responds to the non-final Office Action dated 22 March 2005 (Paper No. 20050301). Applicant has amended claim 40 to correct a minor informality not related to patentability. Applicant also respectfully traverses the Examiner's rejection of the claims. No new matter has been added. Accordingly, claims 1 to 44 are presently pending in the application, each of which Applicant believes is in condition for allowance. Applicant respectfully solicits reexamination and reconsideration in light of the present Amendment and the following remarks.

Allowable Subject Matter

Applicant notes that claims 2, 5, 12, 28, 41, 42 and 44 appear to be allowable. None of these claims has been rejected as being anticipated or obvious in view of the applied art. Therefore, Applicant requests a formal indication of allowance of these claims.

Drawings

In the Action, the Examiner objected to the drawings under 37 C.F.R. § 18.3(a) as allegedly failing to show every feature of the invention specified in the claims. This objection is respectfully traversed for at least the following reasons:

- The limitation "the first indicator coupled with the first inlet port" recited in claim 1 is adequately illustrated in the drawings. For example, Figure 4 illustrates indication port 420 (located in dilator proximate end 412) in fluid communication with over-insertion drip hole 422 via a second lumen

(shown by phantom lines). According to at least one embodiment, over-insertion drip hole 422 serves to indicate when indication port 420 has penetrated a blood vessel. *See, e.g., pgs. 4-5.*

- The limitation “the second indicator coupled with the second inlet port” recited in claim 2 is adequately illustrated in the drawings. For example, Figure 4 illustrates inlet port 416 (located in dilator distal end 410) in fluid communication with drip hole 418 via a first lumen. According to at least one embodiment, drip hole 418 serves to indicate when inlet port 416 has penetrated a blood vessel. *See, e.g., pg. 4.*
- The limitation “at least the third indicator coupled with at least the third inlet port” recited in claim 5 is adequately illustrated in the drawings. For example, Figures 5 illustrates multiple inlet ports 416 in fluid communication with multiple drip holes 418. In addition, Figure 6 illustrates multiple ports 606_{1-n} described as being in connection with multiple drip holes via multiple flow paths. *See, e.g., pg. 6, lines 1-11.*
- The limitation “the second inlet port and the second indicator, the first inlet port and the first indicator, at least the third inlet port and at least the third indicator” in claim 12 is adequately illustrated in the drawings for at least the reasons set forth above.

- The limitation “the penetration gauge comprising an indicator” in claims 35 and 36 is adequately illustrated in the drawings. For example, according to at least one embodiment, suspended ball 704 in differential pressure gauge 700 serves as an indicator to indicate when first and second inlet ports have penetrated a blood vessel. *See, e.g.*, Fig. 7 & pg. 6, lines 12-23. In addition, in accordance with certain embodiments, arrow/pointer 810 in Figure 8 serves to indicate when first and second inlet ports have penetrated a blood vessel. *See, e.g.*, pg. 6, line 24 to pg. 7, line 4.

Thus, because each of the objected-to limitations is adequately illustrated in the drawings, withdrawal of the objection to the drawings is respectfully requested.

Claim Objections

In the Action, the Examiner objected to claims 1, 2, 5, 12, 35, and 36 as allegedly reciting limitations not illustrated in the drawings. This objection is respectfully traversed for at least the reasons detailed *supra* in connection with Applicant’s traversal of the objection to the drawings. Withdrawal of this objection is therefore courteously solicited.

Claim Rejections – 35 U.S.C. §§ 112, 101

In the Action, the Examiner rejected claims 6-11 under 35 U.S.C. § 112, second paragraph, for alleged indefiniteness. Specifically, claims 6-11 were rejected as

allegedly being improper method/process claims. Applicant respectfully traverses this rejection.

Contrary to the Examiner's allegations, claims 6-11 are apparatus claims, not method/process claims. *See, e.g.*, claim 1, upon which claims 6-11 directly or indirectly depend ("A vascular insertion assembly ..."). As such, claims 6-11 need not recite the "steps involved in the method/process" or the "active, positive steps delimiting how this use is actually practiced," as requested by the Examiner, since a method or process is not recited. Thus, since claims 6-11, being apparatus claims, need not and indeed should not recite "any steps involved in the method/process," the rejection by the Examiner is improper and Applicant courteously solicits withdrawal of this rejection.

The Examiner additionally rejected claims 6-11 under 35 U.S.C. § 101 for essentially the same reasons as those set forth above with respect the § 112 rejections. Thus, for at least the reasons set forth above in connection with the traversal of the § 112 rejections, Applicant additionally traverses the rejection of claims 6-11 under § 101, and courteously solicits withdrawal of this rejection.

Claim Rejections – 35 U.S.C. § 102

A. Claims 1, 3, 4, 13-15, 22, 23 and 35

In the Action, claims 1, 3, 4, 13-15, 22, 23 and 35 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 6,193,670 to Van Tassel et al. ("Van Tassel"). Applicant respectfully traverses this rejection.

Independent claim 1 of the present application recites a vascular insertion assembly comprising, *inter alia*, an insertion sheath comprising a sheath distal end and a sheath proximate end and a first inlet port located about the sheath distal end.

In contrast, although Van Tassel arguably discloses an ejection port 50 disposed in the dilator distal end of a dilator, Van Tassel clearly fails to disclose, teach or suggest *at least* a first inlet port located about the sheath distal end of an insertion sheath. See, e.g., Figs. 1-3 of Van Tassel. For example, as clearly described in the specification of Van Tassel, “... ports 50 will extend out of the distal end of the vascular introducer with which it is used when the tubular member 12 is inserted into the vascular introducer...”. Col. 5, lines 59-60 (emphasis added).

Accordingly, because Van Tassel fails to disclose, teach or suggest each and every limitation of independent claim 1, a *prima facie* anticipation rejection has not been established, and withdrawal thereof is respectfully requested. See, e.g., *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) (“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference”).

With respect to the rejection of claims 22 and 23, in Section 2 of the Action the Examiner states that “Van Tassel discloses the invention as claimed except for a pressure gauge.” Thus, because the Action has effectively conceded that Van Tassel fails to disclose, teach or suggest each and every limitation of claims 22 and 23, a *prima facie* anticipation rejection of these claims has not been established, and withdrawal thereof is respectfully requested.

With respect to the rejection of dependent claim 35, Applicant notes that although this claim has been rejected as allegedly being anticipated by the Van Tassel reference, the independent claim from which this claim depends (namely, claim 1) has not been rejected as being anticipated by the Van Tassel reference. As such, the Action has effectively conceded that the Van Tassel reference does not anticipate each and every element of independent claim 1. Thus, in addition to the novel limitations recited therein, because the Action has conceded that the Van Tassel reference fails to disclose, teach or suggest each and every limitation of independent claim 1, claim 35 is allowable over the Van Tassel reference at least by virtue of its dependency upon this allowable independent claim. Applicant therefore respectfully requests withdrawal of this rejection.

Moreover, aside from the novel limitations recited therein, claims 3, 4, 13-15, 22 and 23, being dependent either directly or indirectly upon allowable base claim 1, are also allowable at least by virtue of their dependency upon allowable claim 1. In addition, claim 35 is also allowable at least by virtue of its dependency upon independent claim 28, which is allowable for at least the reasons set forth *supra* (see the section entitled “Allowable Subject Matter”). Withdrawal of the rejection of each these claims is therefore courteously solicited.

B. Claims 16-21, 29-34 and 37-39

In the Action, the Examiner rejected claims 16-21, 29-34 and 37-39 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 6,179,863 to Kensey et al. (“Kensey”). Applicant respectfully traverses this rejection.

With respect to this rejection, Applicant notes that although dependent claims 16-21, 29-34 and 37-39 have been rejected as allegedly being anticipated by the Kensey reference, neither of the independent claims from which these claims depend (namely, claims 1 and 28) have been rejected as being anticipated by the Kensey reference. As such, the Examiner has effectively conceded that the Kensey reference does not anticipate each and every element of independent claims 1 and 28. Thus, in addition to the novel limitations recited therein, because the Examiner has conceded that the Kensey reference fails to disclose, teach or suggest each and every limitation of independent claims 1 and 28, claims 16-21, 29-34 and 37-39 and 23 are allowable over the Kensey reference at least by virtue of their dependency upon these allowable independent claims. Applicant therefore respectfully requests withdrawal of this rejection.

Claim Rejections – 35 U.S.C. § 103

A. Claims 22-27

In the Action, the Examiner rejected claims 22-27 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Van Tassel in view of U.S. Patent No. 5,725,496 to Peters (“Peters”). Applicant respectfully traverses this rejection.

As detailed above, independent claim 1 is allowable over the applied art. Thus, aside from the novel limitations recited therein, claims 22-27, being dependent either directly or indirectly upon allowable base claim 1, are also allowable at least by virtue of their dependency upon allowable claim 1. Withdrawal of the rejection of each these claims is therefore courteously solicited.

Moreover, with respect to claims 25-27 the Action alleges that “it is very well known in the art to use a ball float gauge.” Section 2, page 5 of Action. However, contrary to court precedent, the Examiner fails to provide an affidavit or reference in support of this allegation of obviousness. Accordingly, Applicant hereby timely challenges this assertion of fact as not properly officially noticed. *See MPEP 2144.03.*

As explained in the MPEP, “[o]fficial notice unsupported by documentary evidence should only be taken by the Examiner where the facts asserted to be well-known, or to be common knowledge in the art are capable of instant and unquestionable demonstration as being well-known.” MPEP 2144.03 (emphasis added). Moreover, “[a]llegations concerning specific ‘knowledge’ of the prior art, which might be peculiar to a particular art should also be supported and the appellant similarly given the opportunity to make a challenge.” *In re Pardo and Landau*, 684 F.2d 912, 917, 214 USPQ 673, 677 (CCPA 1982). The Federal Circuit has also held that the Patent Office must demonstrate that the alleged support existed at the time the claimed invention was made. *In re Merck & Co., Inc.*, 800 F.2d 1091, 1093, 231 USPQ 375, 379 (Fed. Cir. 1986).

Thus, if the Examiner believes that claims 25-27 still read on a prior art reference, the Applicant hereby requests that the Examiner:

- (a) Provide another non-final Office Action withdrawing Official Notice and applying a suitable reference for the asserted rejection;
- (b) Issue another rejection under an appropriate statutory provision and provide an affidavit or

suitable reference attesting to all the elements taken
as Official Notice; or
(c) Withdrawal the asserted rejection.

By this reply, Applicant has timely challenged the Examiner's Official Notice and respectfully request that claims 25-27 be allowed.

B. Claim 36

Claim 36 was rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Van Tassel in view of U.S. Patent No. 6,193,670 to Seward ("Seward"). Applicant respectfully traverses this rejection.

As detailed above, independent claim 28 is allowable as not being rejected by any of the applied references of record. Thus, aside from the novel limitations recited therein, claim 36 is also allowable at least by virtue of its dependency upon allowable claim 28. Withdrawal of the rejection of this claim is therefore courteously solicited.

C. Claim 40

The Examiner rejected claim 40 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Van Tassel in view of U.S. Patent No. 5,807,326 to O'Neill et al. ("O'Neill"). Applicant respectfully traverses this rejection.

Independent claim 40 recites a vascular insertion assembly comprising, *inter alia*, an insertion sheath having a sheath distal end and a sheath proximate end and means for providing penetration information located about the insertion sheath.

As conceded in the Action, Van Tassel fails to disclose, teach or suggest "a means for providing penetration information". Pg. 6, Section 5 of Action. Thus, in

order to establish a *prima facie* obviousness rejection, the Examiner must at least demonstrate that the applied O'Neill reference discloses, teaches or suggests the conceded deficiencies of Van Tassel, coupled with a showing of the requisite motivation to combine and/or modify the applied references. The O'Neill reference, however, clearly fails to remedy the conceded deficiencies of Van Tassel.

Although O'Neill arguably discloses forming a colored coating 140 over wire 134 so that it is visible through the walls of a cannula C, O'Neill clearly fails to disclose, teach or suggest *at least* means for providing penetration information located about the insertion sheath. *See, e.g.*, col. 14, lines 40-55. As clearly demonstrated in Fig. 15, the colored coating 140 of O'Neill is located about wire 134, not sheath 136.

Accordingly, because Van Tassel and O'Neill, either alone or in combination, fail to disclose, teach or suggest each and every limitation of claim 40, a *prima facie* case of obviousness has not been established, and withdrawal of this rejection is respectfully requested. *See, e.g.*, *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974); *accord*. MPEP 2143.03.

C. Claim 43

Claim 43 was rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Van Tassel in view of U.S. Patent No. 6,193,670 to Seward ("Seward"). This rejection is respectfully traversed.

As detailed above, independent claim 40 is allowable over the applied art. Thus, aside from the novel limitations recited therein, claim 43, being dependent upon allowable base claim 40, is also allowable at least by virtue of its dependency upon

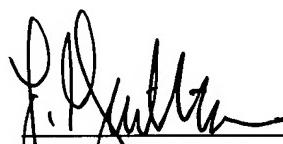
allowable claim 40. Withdrawal of the rejection of this claim is therefore courteously solicited.

Conclusion

For at least the foregoing reasons, Applicant believes that each of the presently pending claims in this application is in immediate condition for allowance. Accordingly, Applicant respectfully requests the Examiner to pass this application to issue. If the Examiner has any comments or suggestions that could place this application in even better form, Applicant invites the Examiner to telephone the undersigned attorney at the above-listed number.

Respectfully submitted,

Date: 20 JUNE 2005



J. Grant Foster
Registration No. 33,236